Endoscopy
Smith & Nephew, Inc.
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Andover, MA 01810

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NOV 23 2005

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K050209

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Control Digital Operating Room System

Date Prepared: January 27, 2005

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew Control Digital Operating Room System
Common Name:	Endoscopes and accessories, Arthroscopes, Electrosurgical cutting and coagulation device and accessories
Classification Name:	General and Plastic Surgery, Orthopedic, Gastroenterology/Urology

D. Predicate Devices

The Smith & Nephew Control Digital Operating Room System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Olympus EndoALPHA

Integrated Endosurgery System, cleared in K981993, HERMES Operating Room Control Center, cleared in K990691, and the Sidne™ System, cleared in K022393.

E. Description of Device

The proposed Smith & Nephew Control Digital Operating Room System is a computer based system that enables centralized status display and control of multiple medical and non-medical devices through touch panel activation or through an optional voice recognition feature. The primary system consists of a Medical Device Controller, Medical Device Hub, Primary Touch Panel Interface (TPI-P), Surgical Touch Panel Interface (TPI-S), Ethernet Router and AVB network hub and AVB Power Supply.

Optional components include:

- speech recognition engine
- a wireless microphone for speech recognition
- a wireless touch screen interface that can be bagged and placed in the sterile field
- a display controller which allows device settings and conditions to be displayed on the surgeon's monitor

F. Intended Use

The Smith & Nephew Control Digital Operating Room System is indicated for use with compatible endoscopic and surgical equipment for centralized control of these devices and display of device status. The control system provides centralized touch panel and voice control of medical devices for use by the surgeon and O.R. staff.

G. Comparison of Technological Characteristics

The Smith & Nephew Control Digital Operating Room System is substantially equivalent to the Olympus EndoALPHA Integrated Endosurgery System, cleared in K981993, HERMES Operating Room Control Center, cleared in K990691, and the Sidne™ System, cleared in K022393 based on the following similarities:

- a central controller which monitors and controls various medical devices
- a centralized control panel which displays various medical devices used in the operating room
- remote control of various medical devices via a touch screen panel
- voice activation and control of various medical devices used in the operating room

H. Summary Performance Data

The performance testing conducted on the Smith & Nephew Control Digital Operating Room System demonstrates substantial equivalence to the Olympus

EndoALPHA Integrated Endosurgery System, cleared in K981993, HERMES Operating Room Control Center, cleared in K990691, and the Sidne™ System, cleared in K022393 based on equivalent performance outcomes of centralized and remote control of medical devices in the O.R.

The Smith & Nephew Control Digital Operating Room System conforms to the following voluntary standards:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (1988) + Amendment 1 (1991) + Amendment 2 (1995) (UL 2601-1)

IEC 60601-1-1 Medical Electrical Equipment – Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems (1992) + Amendment 1 (1995), (2000)

IEC 60601-1-2 (2001-09) 2nd Edition Medical Electrical Equipment – Part I: General Requirements for Safety; Electromagnetic Compatibility – Requirements & Tests (2001)

UL 60601-1 (2003): Medical Electrical Equipment – Part 1: General Requirements for Safety

CAN/CSA 22.2 No. 601.1 Medical Electrical Equipment - Part 1: General Requirements for Safety (1990) + Supplement No. 1-94 (1994)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2005

Ms. Janice Haselton,
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
150 Minuteman Road
Andover, Massachusetts 01810

Re: K050209
Trade/Device Name: Smith & Nephew Control Digital Operating Room System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 17, 2005
Received: October 18, 2005

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkersen
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050209

Device Name: The Smith & Nephew Control Digital Operating Room System

Indications For Use:

The Smith & Nephew Control Digital Operating Room System is indicated for use with compatible endoscopic and surgical equipment for centralized control of these devices and display of device status. The control system provides centralized touch panel and voice control of medical devices for use by the surgeon and O.R. staff.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechbuhler MXM

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050209